K051743

JUL 25 2005

Section 2.1

510(k) Summary
Prepared May 31, 2005

Submitted by:	R2 Technology, Inc. 1195 W. Fremont Avenue Sunnyvale, CA 94087
Contact Person:	Denise F. Gottfried MS/MBA RAC Vice President of Regulatory, Quality, Clinical and Medical Affairs
Product Name:	R2 Breast Imaging Workstation
Common Name:	Medical Imaging Workstation
Classification:	LLZ; Class II; CFR 21 892.2050
Predicate Device:	Sectra Imaging Workstation IRS5/mx.net (K033712)

Description of Device:
The R2 Breast Imaging Workstation is a combination of dedicated computer software and hardware. The workstation consists of a commercially available imaging workstation and the R2 plug-in software application, which is compatible with the workstation through a Clinical Application Interface (CAI).

Intended Use:
The R2 Breast Imaging Workstation is intended for the manipulation and display of x-ray images, including the primary reading of mammograms. It can show images from different acquisition/scanning devices and interfaces to various image storage and printing devices using DICOM or similar interface standards. Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians and assistants.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.

Comparison with Predicate Devices:
The submission device and the predicate device have the same intended use and equivalent technological specifications. All devices support DICOM protocol for communication of images and other medical imaging devices.

Studies:
The R2 Breast Imaging Workstation will undergo design verification tests for conformance with specifications.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K051743 Third Party Organization: Underwriters Lab. Inc

Third Party's Primary Reviewer(s): Morten Simon Christensen

ODE/OIVD Division: DRARD Branch/Team: RADB

Section 2 – 510(k) Decision

Third party recommendation: SE ✓ NSE ____ Other (specify): ____

ODE/OIVD final decision: SE ✓ NSE ____ Other (specify): ____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review		✓	
b. Extent of pre-submission consultation with ODE/OIVD division		Moderate	
c. Organization and format of review documentation			
d. Determination of 510(k) administrative completeness (screening review)	✓		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	✓		
g. Rationale for conclusions and recommendation		✓	
h. Use of guidance documents and standards	✓		
i. Resolution of 510(k) deficiencies and FDA requests for additional information		✓	
j. Scope of reviewer expertise and use of consulting reviewers			
k. Other (specify):			

Comments (explanation of ratings/issues): ____

Section 4 – ODE/OIVD Assessor Information

Assessed by: K Chaknbarti Date: 7/19/05 Tel. No.: 301-594-1212

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2005

R2 Technology, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Service
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K051743
Trade/Device Name: R2 Breast Imaging Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 14, 2005
Received: July 18, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 2.2 Indications For Use

Device Name: The R2 Breast Imaging Workstation

The R2 Breast Imaging Workstation is intended for the manipulation and display of x-ray images, including the primary reading of mammograms. It can show images from different acquisition/scanning devices and interfaces to various image storage and printing devices using DICOM or similar interface standards. Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians and assistants.

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Prescription Use ✓

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051743